~~33~~ 17. The method of Claim ~~32~~ 16, wherein the formulation is administered using a continuous infusion system.

~~34~~ 18. A method for treating diabetes comprising administering an effective dose of the formulation of Claim ~~29~~ 13 to a patient in need thereof.

~~35~~ 19. A method for treating ~~hypoglycemia~~ hyperglycemia comprising administering an effective dose of the formulation of Claim ~~29~~ 13 to a patient in need thereof.

Remarks

Applicants respectfully request entry of the proposed amendments. In an effort to speed prosecution, the subject matter as presented in rejected Claims 1, 3, 7, 8, and 10-16 has been canceled. Applicants reserve the right to prosecute this canceled subject matter in a Divisional Application.

The Examiner indicates that originally filed Claims 2, and 4-6 are allowable if presented in independent form and Claim 9 is allowable if rewritten to overcome the rejection under 35 U.S.C. § 112. The Examiner further notes that the prior art of record does not teach the combination of $Lys^{B28}Pro^{B29}$-human insulin, TRIS, zinc, and a phenolic perservative.

The subject matter in originally filed Claims 2, and 4-6 is represented in new Claims 17-27. New Claims 17 and 18 correspond to original Claim 2.

New Claims 19 and 20 correspond to original Claims 4 and 5; however, in Claim 20 instead of the $Lys^{B28}Pro^{B29}$ concentration being expressed in units, the concentration range is expressed

as mg/mL. Support for expression of the $Lys^{B28}Pro^{B29}$ concentration as mg/mL can be found on page 15, lines 11-19.

New Claims 21-27 depend directly or indirectly on Claim 17 and thus, being narrower in scope, also present allowable subject matter. Dependent Claims 21-25 provide $Lys^{B28}Pro^{B29}$ concentration ranges that are within the broad range provided in Claim 20. Support for these ranges can be found on page 15, lines 11-19. Dependent Claim 26 specifies the phenolic as being a mixture of m-cresol and phenol and is based on page 16, line 13 of the specification and original Claim 6. Support for Claim 27 which specifies a concentration for TRIS, isotonicity agent and phenolic can be found throughout the specification for example on page 16, line 11 and line 18; page 20, Example 1; and page 21, Example 3 as well as original Claim 6.

Claim 28 corresponds to Claim 7 as originally filed with the exception that $Lys^{B28}Pro^{B29}$-human insulin is specified as the monomeric insulin analog. Claim 29 corresponds to claim 9 rewritten to overcome the Examiner's §112 rejection. Claim 29 now refers back to Claim 28 using the term " monomeric."

Claims 30-35 are method of treatment claims using the patentable formulations presented in Claims 17 and 29 and thus, are also patentable. Support for these claims can be found throughout the specification for example, on page 5, lines 14-31 as well as pages 17 and 18.

Applicants respectfully request entry of the proposed new claims which do not add new matter and merely adopt the Examiner's comments. Accordingly, Applicants assert that the

amended claims are now allowable over the art of record.

Respectfully submitted,

Mark J. Stewart

Mark J. Stewart
Attorney for Applicants
Registration No. 43,936
Phone: 317-276-0757

Eli Lilly and Company
Patent Division/MJS
Lilly Corporate Center
Indianapolis, Indiana 46285

August 4, 1999